The State of New Hampshire

Department of Environmental Services

Michael P. Nolin
Commissioner

June 22, 2004

August Baur
Director of Technical Services
Smiths Medical ASD, Inc.
10 Bowman Drive
Keene, New Hampshire 03431-0724

CERTIFIED MAIL (7099 3400 0003 0688 2058)
RETURN RECEIPT REQUESTED

NOTICE OF PAST VIOLATION

Dear Mr. Baur:

On March 28, 2003, Smiths Medical ASD, Inc. ("Smiths Medical"), operating at the time as SIMS-Portex, Inc., notified the New Hampshire Department of Environmental Services, Air Resources Division ("DES") in writing of a permit deviation that resulted in excess emissions of ethylene oxide. Smiths Medical reported releasing between 13.2 to 15.2 pounds of ethylene oxide to the ambient air during a 12-hour period on March 15 and 16, 2003 after a current-limiting resistor, necessary for determination of pressure in the sterilization chamber, failed during the ethylene oxide inject cycle on Chamber #2.

Background

DES issued Title V Operating Permit TV-OP-028 to Smiths Medical on July 21, 2000 for the operation of five ethylene oxide sterilizers. Smiths Medical manufactures medical devices which are sterilized with ethylene oxide to kill any microorganisms. Emissions from the sterilizers are controlled by two emission control devices. The Chemrox wet scrubber removes the ethylene oxide during each sterilizer's vent cycle, by absorbing the gas and converting it to ethylene glycol. The Dec-E-Tech catalytic oxidizer destroys ethylene oxide that is released from the sterilized products while they are placed in the Hot Cells or Quarantine Rooms to allow for off-gassing of any remaining ethylene oxide. DES issued Temporary Permit FP-T-0088 ("the Temporary Permit") to Smiths Medical on April 30, 2002 for the operation of two additional ethylene oxide sterilizers. Condition VIII.A of the Temporary Permit requires Smiths Medical to perform performance testing of the emission control devices within 180 days of the startup of the second sterilizer. Smiths Medical informed DES that the second sterilizer began operation on March 28, 2003.

Each sterilization chamber has a pressure relief valve set to release at a pressure of 15.0 pounds per square inch absolute ("psia"). Under normal circumstances, the chamber is first evacuated, and then injected with ethylene oxide gas. The primary controller during the injection phase sends a signal through a current-limiting resistor that, among other things, allows the system to measure the increase in pressure in the chamber due to the injection of ethylene oxide. When the differential pressure reaches 4.4 psia, the injection phase is supposed to end. On the evening of March 15, 2003, Chamber #2 was injected with ethylene oxide. The current-limiting resistor failed and prevented the differential pressure signal from being read by the controller. With no differential pressure signal to terminate the injection, the chamber continued to fill until pressure in the chamber reached 15.1 psia, exceeding the relief valve setpoint and opening the valve. Ethylene oxide was released into the ambient air at the rate of approximately 2 pounds of gas every 30 minutes, until the sterilizer pressure dropped to 14.8 psia, allowing the relief valve to re-seat. The cycle of opening and closing the relief valve, and the over-pressuring and releasing of ethylene oxide, continued for approximately 12 hours until the following morning on March 16, 2003.

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Smiths Medical notified DES verbally of the process malfunction and excess emissions on March 17, 2003. Smiths Medical investigated the cause of the malfunction, and believes that it was caused by an overheated current-limiting resistor. The resistor may have failed due to age (16 years) or from excessive current. As a result, all resistors on all sterilization chambers were replaced. It was also noted that each sterilization chamber controller was pre-programmed to vent the chamber to the Chemrox wet scrubber in the event of an over-pressure condition. When the sterilization chamber pressure reached 15.0 psia, the controller was to vent the ethylene oxide in the chamber to the Chemrox wet scrubber, preventing it from being released into the ambient air. Smiths Medical discovered that the over-pressure abort condition could only be initiated during the sterilization cycle following injection of ethylene oxide, not during the injection cycle. Smiths Medical has modified the programming since the investigation of the incident to accommodate an abort condition in each sterilization phase in which ethylene oxide is present in the chamber. Finally, the relief valve setpoint has been increased to 30 psia on each sterilization chamber, and an alarm signal is now sent to the facility's Honeywell alarm system in the event of a sterilization chamber over-pressure condition to allow for 24-hour monitoring of chamber pressures.

Smiths Medical calculates that it released between 13.2 and 15.2 pounds of ethylene oxide during the malfunction. Condition VI.J of the Temporary Permit requires that the Chemrox wet scrubber achieve at least 99.0 percent destruction of the ethylene oxide. If the malfunction had not occurred, and Chamber #2 had been filled to its normal capacity without lifting the relief valve, the ethylene oxide from the sterilizer would have been vented to the Chemrox wet scrubber, and 99 percent of the ethylene oxide would have been destroyed. Instead, over a period of 12 hours during the malfunction of Chamber #2, ethylene oxide was released into the ambient air without any control.

Violation

Based upon the information above, DES has identified the malfunction of Chamber #2 on March 15 and 16, 2003 and the resulting excess emissions of ethylene oxide to be a violation of the Title V Permit and the Temporary Permit.

In addition to the above violation, during the preliminary stack testing of the emission control devices on May 29, 2003, the results of the testing indicated that the Chemrox wet scrubber was not operating in compliance with the minimum ethylene oxide removal efficiency as required by Condition VI.J of the Temporary Permit. The preliminary testing was intended to follow EPA's Test Method 25A. However, only three-20 minute runs were accomplished, and the analyzer measuring the concentration of ethylene oxide from the outlet of the Chemrox wet scrubber could not be calibrated according to the EPA method. The results of the preliminary testing indicated that the Chemrox wet scrubber was only achieving a destruction efficiency for ethylene oxide of 97 percent. Smiths Medical found that the scrubber liquid, as indicated by a backup mechanical rotameter, was only flowing at 25 gallons per minute ("gpm"). The primary flow controller indicated a flow of 40 gpm, which is considered by Smiths Medical to be the standard operating flowrate. Smiths Medical increased the flowrate of the scrubber liquid to 40 gpm, and adjusted the flow controller to agree with the backup mechanical rotameter. The flow controller was subsequently replaced with a new unit.

The results of the preliminary testing on May 29, 2003 indicated that Smiths Medical was not operating in compliance with the 99 percent minimum ethylene oxide removal efficiency as required by Condition VI.J of the Temporary Permit. However, in the absence of verifiable quality-assured test data, DES is not citing this occurrence as a violation of the Temporary Permit. Smiths Medical did perform an acceptable performance test of both emission control devices within 180 days of startup of the second sterilizer. Successful performance tests of the Dec-E-Tech catalytic oxidizer and the Chemrox wet scrubber were performed on September 22 and September 23, 2003, respectively.

DES believes that Smiths Medical has taken the appropriate corrective actions in response to the violations and that no further action in response to the listed violation or potential violation is required. Should additional violations occur in the future and DES determines that enforcement is necessary, such actions may include issuing an administrative order, seeking administrative fines, and/or referring this matter to the New Hampshire Department of Justice for civil and/or criminal penalties.

If you believe that DES has cited this violation in error, or if you have questions regarding these matters, please contact Raymond Walters at the Compliance Bureau, Air Resources Division, at (603) 271-6288. A current copy of the Air Resource Division rules can be obtained from the DES website at *http://www.des.state.nh.us/ard/ardrules.htm*, or by contacting the Public Information Center at (603) 271-2975.

Sincerely,

COPY

Pamela G. Monroe
Compliance Bureau Administrator
Air Resources Division

PGM/raw

cc: G. Hamel, DES Legal Unit
R. Kurowski, EPA Region I
J. MacLean, City Manager, City of Keene
File AFS# 3300500043